Clinical trial results:
The influence of exercise and hydration to the pharmacological response to inhaled terbutalin and salbutamol in men

Summary

EudraCT number	2013-000483-29
Trial protocol	DK
Global end of trial date	28 August 2014

Results information

Result version number	v1 (current)
This version publication date	09 February 2017
First version publication date	09 February 2017

Trial information

Trial identification

Sponsor protocol code	Wada_2012

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bispebjerg University Hospital
Sponsor organisation address	Bispebjerg Bakke 23, Copenhagen, Denmark, 2400
Public contact	Respiratory Research Unit, Bispebjerg University Hospital, mhostrup@nexs.ku.dk
Scientific contact	Respiratory Research Unit, Bispebjerg University Hospital, mhostrup@nexs.ku.dk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	17 March 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 August 2014
Global end of trial reached?	Yes
Global end of trial date	28 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the pharmacokinetic effekt of the medicine under physical work and dehydration in healthy men

Protection of trial subjects:

Safety of the trial subjects was high prioritized. All procedures are well tolerated and at risk periods, the subjects were under surveillance so that a member of staff could intervene if needed. The study was performed under the GCP-guidelines.

Background therapy:

None

Evidence for comparator: -

Actual start date of recruitment	07 May 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	30
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started on the 11th of September 2013 and ended on the 01st of july 2014.
Recruitment took place in Denmark, mostly in the greater Copenhagen area.

Pre-assignment

Screening details:

Screening consisted of
Doctors examination
ECG and pulmonary function testing
incremental test

Pre-assignment period milestones

Number of subjects started	30
Number of subjects completed	30

Period 1

Period 1 title	Intervention (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Salbutamol

Arm description:

Active substance: salbutamol

Arm type	Active comparator
Investigational medicinal product name	Ventoline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

The subjects inhale 2x800 µg ventoline at either V1 or V2. At the other visit the subject recieves placebo.
At visit 3 and 4 the subjects inhale 2x800 µg ventoline.

Arm title	Terbutaline

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Terbutaline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder
Routes of administration	Inhalation use

Dosage and administration details:

8x 0.5 mg

Number of subjects in period 1	Salbutamol	Terbutaline
Started	15	15
Completed	15	13
Not completed	0	2
Protocol deviation	-	2

Baseline characteristics

Reporting groups	
Reporting group title	Salbutamol
Reporting group description: Active substance: salbutamol	
Reporting group title	Terbutaline
Reporting group description: -	

Reporting group values	Salbutamol	Terbutaline	Total
Number of subjects	15	15	30
Age categorical Units: Subjects			
Adults (18-64 years)	15	15	30
Gender categorical Units: Subjects			
Male	15	15	30

End points

End points reporting groups	
Reporting group title	Salbutamol
Reporting group description: Active substance: salbutamol	
Reporting group title	Terbutaline
Reporting group description: -	

Primary: Urine concentrations of terbutaline	
End point title	Urine concentrations of terbutaline
End point description:	
End point type	Primary
End point timeframe: During whole trial	

End point values	Salbutamol	Terbutaline		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	13		
Units: ng/ml				
number (not applicable)	15	13		

Statistical analyses

Statistical analysis title	Repeated-measures analysis
Statistical analysis description: Three factorial repeated-measures analysis of variance mixed linear model	
Comparison groups	Salbutamol v Terbutaline
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
P-value	≤ 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Confidence interval	
level	95 %
sides	1-sided
Variability estimate	Standard deviation

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
During the whole trial	
Assessment type	Systematic

Dictionary used	
Dictionary name	Nathional authority
Dictionary version	x

Reporting groups	
Reporting group title	Salbutamol
Reporting group description:	
Active substance: salbutamol	
Reporting group title	Terbutaline
Reporting group description: -	

Serious adverse events	Salbutamol	Terbutaline	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Salbutamol	Terbutaline	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 15 (0.00%)	0 / 15 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No non-serious adverse events were recorded

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27167471

http://www.ncbi.nlm.nih.gov/pubmed/26044066